

REMARKS

Applicants would like to thank the Examiner for the interview conducted on January 27, 2011. The Examiner's comments and feedback were highly appreciated.

Claims 1-19 and 21-31 are pending in the application. Claims 1-14, 16-19, 21-25, 27 and 28 were rejected. Claims 5, 6, 7, 12, and 23 were amended to correct grammatical errors or provide further description. These amendments were made solely for responding to this Office Action and are not to be construed as acquiescing to the Examiner's position nor surrender of any subject matter. Applicant's reserve the right to pursue the amended or canceled subject matter in one or more divisional or continuation applications. No new matter has been added by virtue of these amendments and entry is respectfully requested.

Claim Objections

Claim 7 was objected to for grammatical informalities. Claim 7 was amended as per the Examiner's recommendation.

In view of the foregoing, Applicants respectfully request withdrawal of the Examiner's objection.

Claim Rejections Under 35 U.S.C. § 112

Claim 5 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants respectfully traverse. However, in order to compact and expedite prosecution, Applicants have amended claim 5 to recite human SOCS3. No new matter has been added by virtue of this amendment and entry is respectfully requested.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claims 7, 12-14, 16-19, 21-25 were rejected under 35 U.S.C. § 112, first paragraph.

Applicants respectfully traverse. The Examiner asserts that the specification is not enabling for a cell comprising a vector. Without acquiescing to the Examiner's position, Applicants have amended the claims to recite "isolated." Applicants also disagree with the Examiner's assertions that the specification does not provide enablement for preventing an inflammatory disease. In addition, Applicants respectfully disagree with the Examiner's assertions on pages 4 through to 12 which contain the Examiner's reasoning for rejecting these claims. However, in order to compact and expedite prosecution, Applicants have amended the claims to remove reference to the term "preventing." Since the defendant claims (claims 12-14, 16-9, 21, 22, 24, and 25) incorporate all the limits of the independent claims, these claims no longer incorporate the term "preventing." Applicants have also amended the claims to recite that the SOCS molecule is SOCS1 or SOCS3. These amendments are not to be construed as surrender of any subject matter. Applicants reserve the right to pursue the amended subject matter in one or more continuation or divisional applications.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claim Rejections Under 35 U.S.C. § 103

Claims 1-4, 6-11, 27, 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hilton *et al.* (US Patent 6,323,317) in view of Lin *et al.* (WO 99/49879).

Applicants respectfully traverse.

As the Examiner acknowledges, Hilton *et al.* do not teach a polypeptide comprising a SOCS sequence and a membrane translocating sequence. In addition the Examiner acknowledges that Hilton *et al.* also do not teach a nucleic acid encoding a polypeptide comprising a SOCS sequence and a membrane translocating sequence. However, the Examiner maintains the position that it would be obvious to one of skill in the art to combine Lin *et al.* Hilton and arrive at the instant

invention. Applicants respectfully disagree. First, out of the exceedingly large number of intracellular proteins (greater than 10,000 on average) that are known, including among them large numbers of anti-inflammatory molecules, the different types of membrane penetrating sequences that are available, would require unlimited and undue experimentation without the teachings of the instant invention. Neither of the references provide any reasoning as to why these two particular proteins should be brought together in the manner taught by Applicants. Second, since SOCS function as intracellular signaling proteins with a very short half-life, one of skill in the art would not have been motivated to combine Hilton *et al.* with Lin *et al.* to import a protein with a very short half-life into a cell as such a treatment would require a constant administration into a patient. Third, neither of these references provide any guidance or teachings to engineer the actual proteins disclosed in the instant invention. Fourth, the engineered proteins taught by Applicants provide for controlled delivery of SOCS for the replacement of depleted stores of intracellular physiologic protein, a feasible alternative to gene transfer of SOCS3. Fifth, Applicants have been able to provide for the “**controlled delivery**” of the SOCS protein resulting in one of skill in the art to be able to correctly dose the amount of SOCS needed for therapy. One of skill in the art based on the combination of cited references would not conceive of importing protein with a very short half-life, especially in view of the fact that it would not be feasible nor provide the ability to control the amounts of SOCS in the target cell. Without the guidance and teachings of the instant invention, these two references fail to rise to the level of obviousness, even in view of *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007).

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claims 12, 13, 14, 23, 24 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shouda *et al.* (*J. Clin. Invest.* 108(12): 1781-1788, 2001) in view of Hilton *et al.* (US Patent 6,323,317) and Lin *et al.* (WO 99/49879).

Applicants respectfully traverse.

The Examiner alleges that the injection of an adenovirus vector carrying a SOCS3 cDNA renders Applicants' invention obvious in view of Hilton *et al* and Lin *et al.* Applicants respectfully disagree with the Examiner's allegations. The Examiner acknowledges that Shouda *et al.* do not teach a recombinant protein comprising a SOCS sequence and a membrane translocating sequence. As discussed above, it would not be obvious to one of ordinary skill in the art to combine SOCS and MTS including the Shouda *et al* study. In addition, since SOCS has a very short half-life, and assuming *arguendo*, that one of ordinary skill in the art did combine Hilton et al. and Lin et al., one of skill in the art would rather incorporate the SOCS in a an expression vector so as to prevent the degradation of SOCS until the expression vector containing the SOCS nucleic acid sequence was in the cell. With Shouda et al., further describing the use of vectors to express proteins, one of skill in the art would be taught away from using a protein with a very short half-life in the treatment of inflammatory diseases. Rather one of skill in the art would be directed to a vector expressing such a SOCS protein. Thus, neither Hilton *et al.* in view of Lin *et al.* provide the necessary motivation to combine the SOCS and MTS as taught by Applicants. This is in stark contrast to Applicants invention which is directed *inter alia*, to the importation of the therapeutic SOCS proteins into cells and can be systemically disseminated throughout various cells, tissues, organs and fluids rendering a superior therapy.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

CONCLUSION

Applicants invite the Examiner to call the undersigned if it is believed that the above restriction election is incomplete or improper in any way, or if a telephonic interview will expedite the prosecution of the application to an allowance.

The Commissioner for Patents and Trademarks is hereby authorized to charge any deficiency or credit any overpayment in any fees paid on the filing, or during prosecution of this application to Deposit Account No. 14-1437.

Dated: February 16, 2011

Respectfully submitted,

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